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THE EFFECTIVENESS OF BICITRA AS A PREOPERATIVE ANTACID

by

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Abbott Northwestern Hospital Thesis

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The Effectiveness of Bicitra* as a Preoperative Antacid

INTRODUCTION

The administration of a safe and effective anesthetic is a common goal in anesthesia practice. Patient safety has always been and will continue to be in the forefront of our concern. The adverse results of inappropriate anesthetic management can alter the course of a patient's life and may even end that life. The goal therefore is to administer an anesthetic with the understanding of its potential harm to the patient.

Although there are many potential problems that may develop in the care of the surgical patient, the focus of this paper and the research that was done was to determine what can be done to minimize the potential for the development of aspiration pneumonitis upon the induction and emergence of anesthesia. I will begin by presenting what affect anesthesia has upon the gastric volume and emptying time. Following this will be a summary of what has been done to allay this response in an effort to maintain an appropriate gastric pH and volume. This will include various drug modalities and protocols that have been suggested. The remainder of the paper will be a report of my findings concerning the effectiveness of Bicitra as a preoperative antacid. (2)

ANESTHESIA'S EFFECT ON GASTRIC VOLUME AND EMPTYING

Under normal conditions, the oxyntic (parietal) cells of the stomach secrete an electrolyte solution containing a maximum

* Bicitra is a registered trademark.

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of about 160 millimoles of hydrochloric acid per liter. The pH of this acid solution is approximately 0.8.⁸ If aspirated, this highly acidic fluid would have a devastating effect on the lungs. Also of concern is the amount of acidic solution that is aspirated.

There are three major functions of the stomach which are related directly to motility: (1) the gastric musculature relaxes to allow the stomach to accommodate large volumes ingested during eating and drinking; (2) the stomach contracts and mixes ingested food with gastric secretions, permitting digestion to commence; (3) organized motility occurs to empty partially digested gastric contents into the small bowel.¹⁴ In the preoperative period, gastric emptying is important for three reasons: (1) if drugs are given orally, absorption is erratic and delayed if gastric emptying is inhibited; (2) delayed gastric emptying results in increased volume of gastric contents, which presumably increases nausea and vomiting and delays the reinstitution of normal oral feeding and drug therapy; (3) any increase in volume of acid gastric contents is likely to increase the risk of inhalation of these contents.^{14,16,20}

There are a variety of diseases that seem to modify the rate of gastrointestinal emptying. Pyloric stenosis, Crohn's disease and Coeliac disease all seem to delay emptying to a significant degree. In addition, ketoacidosis, hypocalcemia and

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electrolyte imbalance may cause nausea and vomiting and some delay in emptying of the stomach.

Many drugs have an adverse effect on gastric emptying. The most striking effect is seen in the administration of opioid analgesics.^{1,14} It has been demonstrated that prolonged fasting before surgery does not guarantee an empty stomach at the induction of anesthesia.^{9,14}

For women in labor, the rate of gastric emptying is important because of the risk of aspiration of gastric contents at the time of induction of anesthesia. As a result of uterine changes, the gastric fluid volume tends to be elevated, even if the parturient has been fasting.¹⁶

Nimmo has stated that "it is almost certain that, in the absence of pyloric stenosis or mechanical obstruction to the gastric outlet, opioid analgesic drugs are the major cause of any delayed gastric emptying seen in the preoperative period. Also, that regional anesthesia and other anesthetic drugs seem to be without important effects."¹⁴

ALTERNATIVES TO CONTROL GASTRIC pH AND VOLUME

Anticholinergics: The use of glycopyrrolate has been advocated because of its ability to decrease gastric secretions and increase the pH of gastric contents. However, glycopyrrolate may reduce the tone of the lower esophageal sphincter and increase the incidence of gastroesophageal reflux.

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This could increase the risk of regurgitation and aspiration. This, however, has yet to have been proven.¹³ Anticholinergics can also counteract the desirable effects of metoclopramide (to be discussed later) on gastric peristalsis and the lower esophageal sphincter.¹³ Atropine has also been used and scrutinized for these same reasons.¹⁷

Antacids: Particulate antacids have come under criticism in the past few years for several reasons. First, their routine administration may increase the gastric volume. The second major criticism is that particulate antacid aspiration not only results in initial pulmonary derangement as severe as a highly acidic aspirate, but also histologic abnormalities for as long as one month following aspiration.^{6,9,11,12,13,19} It has been the practice of some institutions to routinely administer particulate antacids every two to four hours with an additional bolus prior to surgery.^{4,15,16} A magnesium trisilicate antacid had been preferred by many in the United Kingdom. It is the agent chosen by the majority of the departments which use some form of prophylaxis.¹⁷ Further, it is chosen in spite of the inconvenience of two hourly administrations (with its increased possibility of a missed dose), the dangers of inhalation of a particulate antacid, reservations about the buffering capacity of the stored agent, and the increase in volume of gastric contents following its administration.^{15,17} Magnesium trisilicate administration to patients often produces nausea and

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vomiting, which may lead to poor staff and patient compliance.⁴ It has been speculated that the failure to prevent obstetric mortality in the United Kingdom is because of the particulate nature of magnesium trisilicate.^{7,18} There are reports of patients dying from pulmonary aspiration syndrome after inhalation of gastric contents containing magnesium trisilicate, and animal work has confirmed severe prolonged lung damage caused by particulate alkalis.^{4,6}

The pulmonary damage following aspiration of a nonparticulate antacid has been shown to be less severe than that following aspiration of a particulate type.^{6,19} The nonparticulate antacid, 0.3M sodium citrate is essentially harmless when aspirated, producing only transient hypoxia and minimal tissue changes.⁵ It has been demonstrated in numerous studies, that 30 ml of 0.3M sodium citrate given before the induction of general anesthesia will maintain the pH of liquid gastric contents above 2.5 in nearly all patients throughout the operation.⁵ Sodium citrate is not available commercially and, therefore, must be prepared by pharmacy. Bicitra, on the other hand, is a commercially available, urinary alkalinizing drug that contains approximately the same amount of sodium citrate as does a 0.3M sodium citrate solution. Laboratory studies indicate that the two agents can buffer comparable amounts of hydrochloric acid. Studies also indicate that Bicitra effectively increases the pH of the stomach contents in nearly

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all patients.⁶ One of the limiting factors in the use of these agents is that their administration must be accomplished less than 60 minutes prior to surgery or effectiveness will be decreased.³

I have already indicated that gastric volume preoperatively is increased in different circumstances. The addition of an antacid in this state will of course increase that volume more. It is evident however that a high volume of nonacidic liquid is better tolerated than even small volumes of acidic liquid.⁶

H₂-receptor Antagonists: Cimetidine and, more recently, the longer acting ranitidine have been demonstrated to effectively reduce gastric acidity and gastric volume by blocking gastric histamine H₂-receptors.^{1,16} H₂-receptor antagonists effectively reduce gastric volumes and acidity, but they require a period of time to achieve, first, a pharmacologically active blood concentration and, second, to exert an inhibiting effect. They cannot affect the pH of the stomach contents present at the time of their administration.¹⁹ It has been shown that patients treated with cimetidine are at a much lower risk of developing pulmonary acid aspiration syndrome if the drug is given between 90 and 150 minutes preoperatively.^{10,12} Obviously, this could be a limiting factor in this drug protocol since the timing of administration of a drug with this degree of accuracy would be impractical.

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Ranitidine has overcome the disadvantage of the shorter duration of action of cimetidine and the need for frequent administration, but it is slower in onset.^{2,19} Ranitidine, because of its longer duration of action, is a more acceptable antacid, especially for use in labor, than cimetidine. Its use presents similar problems to those of cimetidine in that there is a delayed onset and slowed uptake if narcotic analgesics are used.¹⁸ There are other problems associated with the use of H₂-receptor antagonists as the sole antacid. First, there will still be the need for an alkali antacid because of the time factor. Also, as stated earlier, H₂-receptor antagonists cannot elevate intragastric pH rapidly as it is devoid of neutralizing properties for stomach contents already present at the time of administration. Finally, in the parturient, ranitidine and cimetidine do cross the placental barrier and may have an effect on the neonate.⁷

The use of a combination of cimetidine and sodium citrate¹⁹ or ranitidine with sodium citrate^{2,7} can produce the greatest degree of certainty that the gastric pH will be in a safe range. It has been reported that the combination of histamine H₂-receptor blockers with a preoperative nonparticulate antacid is both the most effective and most convenient prophylactic regimen.^{2,17}

Metoclopramide: Metoclopramide has been found to facilitate gastric emptying and also to increase tone in the

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lower esophageal sphincter.¹³ However, it does not reverse gastric hypomotility due to narcotics, nor does it guarantee a completely empty stomach. W.S. Nimmo learned that in studying the absorption of paracetamol in patients in late labor, narcotics produced a marked delay which was not reversed by metoclopramide.¹⁴ Like the H₂-receptor antagonists, it has no direct effect on gastric fluid pH.¹ It is also important to note that its actions can be blocked by the prior administration of atropine or opioids.^{1,20}

STUDY

Abstract

To evaluate the effectiveness of Bicitra as an oral antacid to elevate gastric pH above the critical level of 2.5, 20 patients were studied. The patients were assigned by convenience to two groups. Those in Group 1 served as a control group and received no premedicant prior to induction of anesthesia. Those in Group 2 received 30 ml of oral Bicitra no more than 60 minutes prior to induction of anesthesia with the exception of one patient who received it 100 minutes prior. Gastric fluid was obtained via an orogastric double lumen tube after induction and prior to emergence and analyzed for pH. The Bicitra group had a significantly higher gastric pH on induction

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($p < 0.001$) and upon emergence ($p < 0.01$). Also, 90 percent of the patients in the Bicitra group had a pH greater than 2.5.

Aspiration pneumonitis is an important event in the practice of anesthesia that evokes both fear and concern in the minds of anesthetists. Most articles that I have read agree that the critical factor for the development of aspiration pneumonitis is a pH of less than 2.5 and a gastric volume of 25 ml or greater.^{2,3,6,9,11} It has been discovered in work with rats, that the critical volume depends on the pH of the aspirate.¹³ Even low volumes have a high mortality rate if the pH is low; whereas higher volumes than noted above can be tolerated if the gastric fluid is effectively buffered.¹³ It is for this reason, and also due to the fact that it is difficult to determine if all of the gastric contents have been aspirated when determining gastric volume, that I have chosen not to measure these volumes in this study.

METHODS

I studied 20 patients scheduled for routine surgical procedures that did not involve gastric contamination. Ten of these patients received 30 ml of oral Bicitra in a range of 10-100 minutes prior to induction of anesthesia. After induction of general anesthesia and intubation of the trachea, a #18 Salem

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sump tube was placed in the stomach and placement was verified by auscultation over the epigastrium during insufflation of a small amount of air through the gastric tube. To prevent the contamination of the second lumen of the sump tube with gastric contents, 60 cc catheter tip syringes were connected to either lumen of the Salem tube, a sample of the gastric contents was taken immediately after placement of the tube and its pH was tested using the Baxter S/P pH indicator strips. At the conclusion of surgery and prior to extubation, the contents of the stomach were evacuated through the second lumen of the Salem tube and tested for pH in the same manner as the first sample. This procedure was followed exactly in the same manner for the other 10 patients who had received no preoperative Bicitra. All patients received essentially the same anesthetic induction of Pentathol, Versed, Fentanyl and Norcuron, except two of the patients who were given Atracurium rather than Norcuron.

Statistical analysis of results involved Bonferroni t-test, correlation coefficient, and one-way analysis of variance. The $p \leq 0.05$ level was considered statistically significant. The mean of the pH values (not the $[H^+]$) was calculated.

RESULTS

A summary of the characteristics of the two groups is provided in Table I. There was no significant difference between the two groups concerning age, sex, weight, number of

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hours fasted or ASA classification. It is important to note that there was no significant difference between the ASA of the patient and the pH of the first gastric sample. There was however a significant correlation ($p < 0.05$) between the time NPO and pH of the first gastric sample. This suggested that with increased time NPO, there is a chance that the pH of the gastric contents will be increased also.

Table I
Comparison of Group Characteristics (Mean \pm SEM)

	Bicitra Group	Control Group
Number	10	10
ASA	2.2 \pm 0.25	1.7 \pm 0.21
Age (years)	52.6 \pm 3.3	39.8 \pm 5.8
Weight (kg)	68.8 \pm 4.3	71.9 \pm 5.3
Number of Hours Fasted	10.1 \pm 0.73	11.65 \pm 3.6

Also, statistical analysis revealed a significant difference between the pH of the control group and that of the Bicitra group at a p less than 0.001. This data is summarized in Table II. This indicated that the patients who received Bicitra preoperatively had a gastric pH significantly higher than those patients who did not receive this medication. All patients in the control group had an induction gastric pH of

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less than 2.5 which is the critical pH for the development of aspiration pneumonitis. In contrast, 90 percent of the patients who had received Bicitra preoperatively had a gastric pH that was well above the critical pH of 2.5.

Table II
Gastric pH of Bicitra and Control Groups on Induction
(Mean \pm SD)

	Number (Pts)	pH (units)		pH > 2.5	
		Mean \pm SD	Range	#	%
Bicitra	10	3.59 \pm 0.74	1.8 - 4.5	9	90
Control	10	1.95 \pm 0.4	1.3 - 2.3	0	0

Bonferroni t-test: Shows a significant difference at $p < 0.001$

A correlation was also made of the pH of gastric contents prior to the emergence of anesthesia. This revealed that the mean pH of those who had received Bicitra preoperatively was significantly higher ($p < 0.01$) than those who had had no preoperative medication. This data is summarized in Table III. This information revealed that 90 percent of the patients who had received the Bicitra preoperatively still had a pH greater than 2.5 at the conclusion of surgery. It is interesting to note that the patient whose pH was below 2.5 on induction of anesthesia had a pH that was 3.8 upon emergence from anesthesia.

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Perhaps this indicates that the first sample may have been obtained in an acidic pocket in the stomach and the Bicitra had not been thoroughly mixed with the gastric contents. A correlation coefficient was drawn on the Bicitra group comparing the pH upon induction and at emergence with the time since the Bicitra had been administered to both. It is important to note that there was no statistical significance regarding this correlation. Therefore, the pH did not depend on how long it had been since the patients had had the Bicitra. Keeping in mind that all but one of the patients received the Bicitra less than 60 minutes before induction, it should be understood that this significance surely would have a time limiting factor. Although the patient who had received the Bicitra 100 minutes prior to induction did have a pH of 3.0 on induction of anesthesia, he also was the one patient in the Bicitra group who had a pH less than 2.5 on emergence.

Table III

Gastric pH of Bicitra and Control Groups on Emergence
(Mean \pm SD)

	Number (Pts)	pH (units)		pH > 2.5	
		Mean \pm SD	Range	#	%
Bicitra	10	3.97 \pm 0.77	2.3 - 5.5	9	90
Control	10	2.63 \pm 1.13	1.3 - 5.0	3	30

Bonferroni t-test: Shows a significant difference at $p < 0.01$

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By defining a patient's risk for aspiration pneumonitis as a gastric fluid pH of less than 2.5, the Bicitra group revealed that patients were at a 10 percent risk on induction and at emergence compared to 100 percent of the control patients being at risk on induction and 70 percent of the control patients being at risk on emergence from anesthesia.

DISCUSSION

The prevention of vomiting, regurgitation and aspiration of gastric contents is of paramount importance in the administration of anesthesia. Inhalation of gastric contents is an ever present risk in all patients undergoing surgery. This may occur due to various reasons which include the inability to intubate the trachea at the time of induction, the unexpected onset of vomiting following induction of anesthesia or even vomiting in the conscious regional patient.⁷ This study has demonstrated that there is a potential risk for acid aspiration pneumonitis in patients who have had no premedicant Bicitra in spite of a period of fasting prior to surgery. It is important therefore to adopt an anesthetic protocol that takes into account this potential risk. As has been stated previously, all patients in the control group had a gastric pH of less than 2.5. In contrast, the preoperative administration of an inexpensive nonparticulate antacid safely raised the gastric pH of 9 of the 10 patients to a level that has been

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proven safe in avoiding the development of aspiration pneumonitis.^{3,4,9,12} Although it has been proven that the administration of this volume of Bicitra will raise the volume of the gastric contents,^{3,6,9,12,18,19} it has also been studied and documented that the volume of the gastric contents does not appear to be as important as the pH of those same contents. McCammon stated that the critical volume depends on the pH of the aspirate. He further stated that even low volumes have a high mortality rate if the pH is low; whereas higher volumes than noted (greater than 25 ml) can be tolerated if the gastric fluid is effectively buffered.¹³

Although it has been documented that the administration of cimetidine preoperatively is more effective in reducing gastric volume and raising pH of the same and may be even more effective when combined with a nonparticulate antacid,^{10,12,13,19} oral Bicitra preoperatively has proven to be an effective adjunct in maintaining a safe pH.

Finally, as Charles P. Gibbs stated, "No prophylactic antacids can prevent aspiration of gastric contents; they can only ameliorate the consequence."⁶ Therefore, it is the goal of every anesthetist to allay the potential for the development of aspiration pneumonitis. It has been determined that the use of Bicitra is an effective means in raising the gastric pH above the critical level in nearly all patients studied, and, therefore, it provides a safe environment to work under.

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